510(K) Summary

FEB 8 2013

U.S. Food & Drug Administration – 510k Application

This application for 510k summarizes the safety and effectiveness information in accordance with the requirements of SMDA 1990 and 21 CFR Section 807.92.

The assigned 510(K) number is: K122810

A. General Information

i.	Submitter's Name & Address :	Thermor Limited 16975 Leslie Street Newmarket, Ontario Canada L3Y 9A1
ii.	Telephone	800-387-8520
iii.	Facsimile	866-947-1034
iv.	Contact Person	Mark Beaton
v.	Contact Email	mbeaton@thermor-ins.com
vi.	Date Prepared	September 10, 2012

B. General Information on Device

i.	Name:	Digital Blood Pressure Monitor
ii.	Trade Name:	Compact Digital Blood Pressure Monitor, model BD204
iii.	Common Name:	Blood Pressure Monitor
iv.	Classification Name:	System, measurement, blood pressure, non-invasive
v.	Product Code:	DXN
vi.	Class:	2
vii.	Regulation Number	870.1130

K122810 2/4

C. **Identification of FDA Cleared Device (predicate)**

i. Name: Digital blood pressure monitor, model LD 578

ii. K Number: K061279

iii. Date Cleared: August 18, 2006

D. **Description of the Device**

The Compact Blood Pressure Monitor, model BD204 is designed to measure systolic and diastolic blood pressure and pulse rate of an individual adult by using a non-invasive technique in which an inflatable cuff is wrapped around the upper arm.

Rather than using the ausculatory method, which employs either an aneroid gauge or mercury manometer with a stethoscope to determine systolic and diastolic pressure, the device uses the oscillometric method, wherein an electronic semiconductor - sensor in the cuff determines the measurements. The sensor converts minute alterations in cuff pressure to electrical signals, by analyzing the amplitude of those signals systolic and diastolic pressure and pulse rates are calculated. The device analyses the signals and displays the results immediately.

Oscillometric technology is well established and has been used for decades. The accuracy of this monitor has been validated to the European Hypertension Society protocol.

E. **Intended Use Statement**

Model BD204 Compact Blood Pressure Monitor is intended for use by medical professionals in medical facilities or by patients for self- monitoring at home to monitor systolic, diastolic and pulse rates on a regular basis. This monitor is used in the same manner as the predicate model.

F. **Comparisons to the Predicate**

The modified device (BD204) has the same intended use and identical fundamental technology as the predicate model LD 578. The device employs the same software to analyse the sensor readings using the oscillometric method, common to both monitors. It is identical in safety and effectiveness of the intended use to the 510(K) cleared device: LD 578.

The specific modifications from the original 510K cleared device are: different outer housing shape and size, addition of date and time to LCD readout, and minor modifications to the inflation and exhaust components.

Modifications made from Predicate:

1. Shape and size of housing
2. Date and Time on Display
3. Inflation and exhaust components
4. Packaging and wording in the Instruction manual
5. Includes a UL approved AC/DC adaptor

Tabulated comparisons demonstrating that the model BD204 is substantially equivalent to the predicate device with FDA 510K #K061279:

Technical Characteristics Comparison

Intended Use	Identical
Fundamental Technology Employed	Identical
Target population	Identical
Use: by medical professional or patient	Identical
Safety and Effectiveness	Identical
Over the counter	Identical
Performance Specifications	Identical
Sterility	Not Applicable
Biocompatibility	Identical
Mechanical safety	Identical
Electrical Safety	Identical
Standards Met	Identical
Energy Used or delivered	Identical
Environmental specifications	Identical
Ergonomics of patient user interface	Identical
Software	Identical
Packaging	similar
Dimensional Specification	Somewhat smaller out case
Inclusion of AC/DC Adaptor	Not included with predicate model

G. Discussion of Similarities and Differences

The modified device is identical to the predicate in function and performance. The only differences are: Time & date on the display. The modifications to the original 510(k) cleared device are: the smaller outer housing, different packaging, slight change to inflation and exhaust components, inclusion of AC/DC UL approved adaptor.

The algorithm used to determine the blood pressure values and the software codes are unchanged from the predicate model. The Fundamental technology used by the modified device, is the same as the 510K cleared device.

None of the modifications will have any impact on the safety or effectiveness of the device for measuring blood pressure.

H. Performance Testing

The product has been tested and complies with the following standards:

IEC/EN 60601-1: 2005

The AC/DC adapter was separately evaluated according to EN 60601-1/A2: 1995

I. Conclusions

Compact Digital Blood Pressure Monitor, Model BD204 is as safe and effective as the predicate device in it's intended use for blood pressure measurement based on electrical, mechanical and environmental testing results and the SP-10 standard requirements. Therefore, this device is essentially equivalent to the predicate device for blood pressure measurements.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-002

FEB 8 2013

Thermor Ltd.
c/o Mr. Mark Beaton
Vice President of Marketing
16975 Leslie Street
Newmarket, Ontario
Canada L3Y 9A1

Re: K122810
Trade/Device Names: Compact Digital Blood Pressure Monitor, Model BD204
Regulatory Number: 21 CFR 870.1130
Regulation Name: Noninvasive Blood Pressure Measurement System
Regulatory Class: Class II (Two)
Product Code: DXN
Dated: Undated
Received: December 6, 2012

Dear Mr. Beaton:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Bram D. Zuckerman

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K122810

Device Name: Compact Digital Blood Pressure Monitor

Indications for Use: The Compact Blood Pressure Monitor is intended to measure the systolic, diastolic and pulse rate of an adult individual by using a non-invasive technique in which an inflatable cuff is wrapped around the upper arm. The device is reusable and intended for home use on adults.

Prescription Use _____ AND/OR Over-The-Counter Use X
(21 CFR 801 Subpart C) (Part 21 CFR 801 Subpart D)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K122810